including a head portion with an upper flat surface, said roughened exterior surface beginning about 3 mm below said upper flat surface.

54. (New) An implant of claim 12, wherein said substantially cone-shaped elements have a base having a diameter of about 0.3 to 1.2 microns and said bases are spaced about 0.3 to 0.75 microns from each other.

55. (New) A titanium implant of claim 28, wherein said substantially cone-shaped elements have a base having a diameter of about 0.3 to 1.2 microns and said bases are spaced about 0.3 to 0.75 microns from each other.

56. (New) A titanium device of claim 38, wherein said substantially cone-shaped elements have a base having a diameter of about 0.3 to 1.2 microns and said bases are spaced about 0.3 to 0.75 microns from each other.

## REMARKS

Claims 11-25, 27-33, 35-49 and 51-56 remain in the application for further prosecution. Claims 26, 34 and 50 have been replaced with new claims 51-53. Claims 54-56 have been added, finding support in the Second Preliminary Amendment mailed March 11, 1999. Submitted herewith is a clean set of pending claims.

The Examiner noted that "Claim Amendments" were enclosed in the recent amendment, but were ignored. It appears that the amendments were identical to those previously submitted and that they had been included inadvertently. They should be discarded from the PTO file or noted to be a duplication of amendments previously submitted.

### I. Rejections Under 35 U.S.C. § 112

Claims 11-21 and 27-50 were rejected under 35 U.S.C. § 112 as being unsupported by the specification. More specifically, the Examiner objects to use of the term "substantially" or

"substantially removed" in connection with the degree to which the native oxide layer is removed or the roughness of the final surface. The Examiner takes the position that the specification fails to provide some standard by which the roughness of the surface or the degree of removal of the oxide surface could be determined when the term "substantially" is used. Reconsideration is requested.

The discussion below refers to the additional text provided in amendments mailed March 11, 1999, and February 9, 2001, which introduced the description from parent Application No. 08/607,903 and found at column 4, lines 1-31, and column 4, line 57, to column 8, line 25, of U.S. Patent No. 5,876,453. For convenience, reference will be made to the '453 patent text.

While the term "substantially" may be considered a broad term, it should be understood in this context as leaving open the possibility of some variation which has no significant effect on the property being described. The word "substantially" is often found in patent claims and it has a purpose grounded in facts. Many commonly used terms depend on an assumed context. For example, whether a surface is "smooth" depends on the magnification used by the viewer. It may be smooth to the touch, but appear rough when viewed under a microscope. Thus, the degree of smoothness will depend on the context in which it is used.

Consider the meaning of "substantially uniform surface texture," a phrase which is literally found at column 5, line 29, of the '453 patent. It should be evident from viewing the photographs of FIGS. 3, 4, 6 and 7 that words cannot fully describe the topography of the surface and that the magnification of the photographs presents different perspectives. The naked eye can recognize the acid etched surface to be uniform, but the magnified images show a surface which is uniformly rough. Residual native oxide will limit the ability of the etching acids to create the desired uniformly rough surface. FIG. 3 of parent U.S. Patent No. 5,876,453 is a sketch

illustrating the point. If native oxide (14) remains, then the acids are unable to etch the metal uniformly, since they are unable to remove the native oxide completely. See Example 2.

With regard to use of the word "substantially" in connection with removal of the native oxide, this is literally used at column 5, lines 25-29, of the '453 patent ". . . *it is important to remove substantially all of the native oxide from the implant surface . . . so that subsequent treatment of that surface produces a substantially uniform surface texture . . .*" The method for determining the depth of the native oxide is by AES, as discussed at column 4, lines 1-30, of the '453 patent, and illustrated in FIG. 5 (FIG. 7 of U.S. Patent No. 5,876,453). That conventional technique for measuring the depth of oxides on the surface of metals can assure one skilled in the art that the native oxide has been removed. In the discussion at column 5 of the '453 patent, it is reported that the preferred 15% HF solution can etch the oxide at about 200-350 Angstroms/minute and that in about one-half minute all the native oxide will have been removed, since the native oxide thickness is normally about 70-150 Angstroms. *"The preferred 15% HF solution allows substantially complete removal of the native oxide layer with minimum further consumption of the titanium surface . . ."* (see column 5, lines 18-21, of '453). It should be clear that practicing the techniques taught in the specification will provide a surface which can be considered "substantially" free of native oxide.

Further, the Federal Circuit has consistently ruled that terms like "substantially" or "about" present an acceptable way for the patentee to ensure that he or she will not have to rely solely on the doctrine of equivalents to prove infringement when competitors try to avoid the patent by insignificant changes. See Ahmil Enterprises v. Wawa, Inc., 81 F.3d 1554 (Fed. Cir. 1996); Pannu v. Iolab Corp., 155 F.3d 1344 (Fed. Cir. 1998). For example, in this case, should a future potential infringer fall outside the literal scope of the pending claims because they

purposefully mask off a small 1 mm x 1 mm area on the implant surface so that the native oxide remains? Or, should that same future potential infringer fall outside the scope of the pending claims because they remove 299 Angstroms of the 300 Angstroms of native oxide in certain areas while using the preferred HF solution and then allow the preferred $H_2SO_4$-HCl acid solution to eat away the final 1 Angstrom (which could be done in a short amount of time with the preferred $H_2SO_4$-HCl acid solution) before producing the claimed etched surface? That seems to be what the Examiner suggests by attempting to force the Applicants to not use the term "substantially," yet the U.S. patent laws do not force the Applicants to claim their invention in such a narrow fashion.

Therefore, the Applicants submit that the rejection of claims 11-21 and 27-50 under 35 U.S.C. § 112 should be withdrawn in view of the teachings of the specification.

**II. Rejections Based On Krueger**

Claims 11-16, 22-35, 27-33 and 35-49 were rejected under 35 U.S.C. § 102(b) as anticipated by Krueger or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Krueger. The Examiner states that Krueger teaches *". . . product which has been etched to remove impurities . . ."* and asserts that at least one of the intermediate or final product would have the native oxide layer removed and would have irregularities of less than 10 microns.

The text of the Krueger patent is too vague, however, to support such a conclusion. Krueger says only that the etching techniques correspond to those used in etching the electrodes of electrolytic capacitors. *"For this reason they are not set forth in detail in this specification. Normally concentrated mineral acids are employed to etch such electrodes."* (column 3, line 67, to column 4, line 2). This disclosure could not enable one skilled in the art to understand or duplicate the methods used by Krueger. Therefore, the Applicants contend that the Krueger

reference does not anticipate. A reference cannot anticipate when it does not enable, MPEP 2121, and the vague disclosure of Krueger does not support a prima facie case of obviousness.

**A. Methods For Etching Electrolytic Capacitors**

The Examiner previously provided (Paper No. 21, December 20, 2000) three references (U.S. Patent Nos. 4,093,887 and 5,439,565 and EP 0 616 054) for the proposition that one skilled in the art would understand from the teachings in the electrolytic capacitor art how one should etch titanium implants. The references, however, relate to etching of aluminum and copper, not titanium.

U.S. Patent No. 4,093,887 relates to etching copper in a spark plug electrode by one of several possible methods. With regard to mineral acids, the patentee says, *"[c]opper can also be dissolved by means of mineral acids, such as hydrochloric acid or sulfuric acid in the range of from about 5% to highly concentrated. The acids additionally contain oxidation additives . . . Copper can also be dissolved out by oxidizing acids, such as for example $HNO_3$, to 10% concentrated; $HNO_3$/HCl mixture 1:5 to 5:13, acidic chromate solutions."* Nothing in the foregoing disclosure suggests etching of titanium with an $HCl/H_2SO_4$ mixture after removing the native oxide with HF solution.

U.S. Patent No. 5,439,565 is equivalent to the third reference, EP 0 616 054. They teach electrochemically etching aluminum foil in acid while passing a direct current through the foil. Two stages were used, each having a specific current density. The acid was a mixture of HCl and $H_2SO_4$ in the first stage and the final stage used $HNO_3$ with oxalic acid or one of a group of acids added to increase the diameter of the pits. Although two stages are used, the material being etched was aluminum and the process was very different from that taught by the Applicants.

### B. Steri-Oss 2000 Publication Shows Krueger Is Non-Enabling

The most persuasive evidence to show how purposefully non-enabling Krueger is comes from the owner of Krueger's patent, Steri-Oss. A brochure (attached as Exhibit 1) was published in 2000 by Steri-Oss, the assignee of Krueger. On page 2, Steri-Oss states the following.

> *Prior to the introduction of the first Steri-Oss® System threaded dental implant in 1986, surface research was initiated by Steri-Oss to develop a roughened titanium surface. The result of this research was a patented[1] two-step acid etching procedure which significantly increased the surface area over that of machined titanium implants.* [emphasis added]
>
> [1]U.S. Patent No. 4,826,434 [Krueger]

In other words, before 1986, Steri-Oss was engaged in "surface research" to develop the best roughened surface for its titanium implants. Steri-Oss identified this ideal roughened surface and released a product. Further, on October 20, 1986, Steri-Oss filed the application that led to Krueger's patent, the teaching of which is now at issue.

Considering that Krueger has claims (e.g., claims 3 and 6) directed to the "acid-etched surface," one must question whether Steri-Oss and Krueger disclosed the "best-mode" for carrying out the invention when filing this application, as required by 35 U.S.C. § 112. Steri-Oss performed "surface research" to develop the best surface for its titanium implants, but forgot to instruct the rest of the world how to perform this roughening procedure that Steri-Oss now calls its "patented two-step acid etching procedure." Even the simple fact that Krueger's claimed acid-etched surface is accomplished by a "two-step acid etching" is missing from Krueger's disclosures. Instead, all the skilled artisan learns of the results of Steri-Oss' "surface research" is that if one desires to roughen the surface of a *titanium* dental implant, then they should follow one of the many etching processes that were used for *copper* or *aluminum* electrolytic capacitors.

Consequently, in addition to the fact that Krueger is simply not enabling, Steri-Oss' own admission that its "surface research" led to Krueger's patent, which fails to teach the skilled artisan how to make Krueger's claimed etched surface, is powerful evidence that Steri-Oss and Krueger chose to conceal its roughening methodology as a trade secret. To the contrary, the details of Applicants' two-step etching process were made available to the public and their claims should be patentable over an implant made by an undisclosed (and apparently secret) roughening method. This brochure, published several years after the filing date of the earliest filing date of the parents of the present application, appears to be an attempt by Steri-Oss to suggest that Steri-Oss was in possession of an etching method similar to that of the Applicants, one that is used on *3i*'s Osseotite® implant which has achieved substantial clinical and commercial success as evidenced in the Rule 132 Declaration by Dr. Stephan Porter, discussed below.

Finally, the Examiner is invited to review the 1987 reference (C75) entitled "Steri-Oss System" (Denar) in the accompanying Sixth Information Disclosure Statement. This appears to be the configuration of the first commercial product released by Steri-Oss, the one that arose from Steri-Oss' "surface research." It simply teaches that the surface is a "textured surface" and states on the back cover that the device in this brochure is "patent pending," presumably referring to Krueger's then-filed patent application. Again, this 1987 reference provides no teaching of the details used by Steri-Oss to create this textured surface.

**C. The Examiner's Suggestion For Further Testing**

The Examiner admits that it is not clear from the Krueger patent that the native oxide has been removed, but he assumes that an etching process which increases the surface area by a factor of two would inherently remove the native oxide to the extent claimed by the Applicants.

Thus, he asks the Applicants to show that Krueger does not anticipate or make obvious the present invention. Unfortunately, the Applicants can do no more than the PTO, since the Krueger patent does not provide enough information to enable comparative tests to be made. As discussed above, it appears likely that Krueger avoided disclosing the etching process, intending to keep the process as a trade secret. If so, then it should be evident that it is not possible to compare the Krueger process with the Applicants' process.

As the Examiner knows, it is common in chemical applications to compare an example from a reference with the invention to demonstrate the improvement obtained with the invention. The Applicants cannot provide such a comparison with Krueger since he fails to provide any information which could be used to exemplify his process. A general reference to the use of "mineral acids" is not sufficient. As the Applicants have demonstrated in Example 2, the mixture of the mineral acids HCl and $H_2SO_4$, which is used to roughen a titanium surface, is not adequate to remove the native oxide and, therefore, does not produce a uniformly roughened surface.

**III. Rejection Of Claims 13, 26, 34, 36 and 50**

Claims 13 and 36, relating to the two-step etching process in which the first step removes the native oxide, are considered to be obvious by the Examiner, although the reason for such a conclusion is not understood. Previously issued patents in this series of applications have been found to contain allowable subject matter including the two-step acid etching process.

Claims 26, 34 and 50 were only rejected under 35 U.S.C. § 103(a) as unpatentable (obvious) over Krueger in view of Wagner et al. (Wagner). As the Examiner recognized, Krueger did not teach including both roughened and unroughened sections in his implant. Wagner does teach the use of differing degrees of roughness in his implants. He does not,

however, teach the use of a smooth section which extends about 3 mm down from the top of the implant, typically including the uppermost threads. Instead, Wagner teaches the use of three different types of surfaces, none of which are acid etched. Only one is said to be grit-blasted to roughen the surface in a narrow band near the top. Thus, if one skilled in the art were to look to Wagner, he would have to adapt those teachings radically to use them in the threaded implant of Krueger. There would be three different surface textures, none of them acid etched.

Note that Wagner does not recognize the benefits of providing a roughened surface on threads since, in the alternative embodiment of FIG. 4, the threads apparently are not roughened at all, while the upper portion of the implant remains the same as FIGS. 1 and 3.

Claims 26, 34 and 50 recite the preferred distance (3 mm) which is left unroughened. In contrast, the smooth portion 28 of the Wagner implant is preferably only about 0.75 mm, with a maximum range of 0.25 to 2.0 mm. A similar range is suggested for grit blasted region 26. Thus, it should be evident that Wagner is not sufficient to suggest to one skilled in the art the Applicants' invention.

It appears that Wagner should not be considered to be prior art to the present application, which claims the benefit of earlier applications including PCT/US95/6595 of November 30, 1995. Wagner has a 102(e) date of October 2, 1997, and a PCT publication date of June 19, 1997. Therefore, Wagner is not only insufficient to make present claims 26, 34 and 50 obvious when combined with Krueger, it appears that Wagner is not available as prior art. Therefore, claims 26, 34 and 50 should be allowable and, consequently, they have been cancelled and rewritten as new independent claims 51-53.

## IV. Rejections Based On Schulte

Claims 11-16, 22, 24, 26, 27-33 and 36-49 were rejected for the first time under 35 U.S.C. § 102(b) as anticipated by the Schulte et al. 1992 article (Schulte) or as obvious under 35 U.S.C. § 103(a). The Applicants believe that the Examiner did not intend to reject claim 26 based on the Schulte reference, since 24 and 26 were merged and since the corresponding claims 34 and 50 were not rejected on Schulte.

The Examiner notes that the irregularities are 2-5 microns high and substantially uniform, especially pointing to FIG. 14. The Applicants can agree that the teachings of the Schulte article are not clear, but they cannot agree that the only question is whether the Schulte implant is identical or substantially identical. The Schulte article contains very little information regarding titanium implants, since the main emphasis of the investigations was with aluminum oxide implants. On page 8, the authors begin to discuss the Frialit®-2 system. With regard to the surface of the titanium, they say, *"[t]he titanium surface is sandblasted and etched to achieve a relative increase in area compared to the bone . . ."* FIG. 13 shows the surface of a Frialit-2 stepped screw after blasting with aluminum oxide powder. FIG. 14 shows the surface of the stepped screw after "acid etching." It is not clear whether the surface of FIG. 14 is the result of the aluminum oxide blasting of FIG. 13 followed by acid etching. Even if it is assumed to be the case, the Schulte article is silent on the type of acid etching that was used. One skilled in the art would learn little from such as disclosure. As with Krueger, the implant which results from the process used by Schulte cannot be discerned. The necessary information which one skilled in the art would need to duplicate the Frialit-2 implant has been omitted. Again, as with Krueger, the 1992 article does not disclose enough information to make it an anticipation of the presently claimed implants. Nor, can the Schulte article fairly be said to make the present claims obvious.

In the Third Information Disclosure Statement mailed August 6, 2001, it is explained that Friatec, like Steri-Oss, appears to have chosen to keep the details of its process for roughening their implant surface a trade secret.

## V. Substantial Secondary Evidence Establishes The Claimed Invention Is Not Obvious

The Applicants further support the patentability of the present claims by the attached Rule 132 Declaration of Dr. Stephan Porter, which demonstrates that implants with the claimed surface have achieved commercial distinction in that they are overwhelmingly preferred by dental clinicians. This surface, commercially referred to as the Osseotite® surface, is present on over 94% of all of the assignee's implants that were sold in 2001. Considering that virtually the same sized implants are offered by the assignees with both TPS surfaces and machined surfaces, it is quite remarkable that clinicians prefer the Osseotite® surface on the implants they install by a ratio of over 9 to 1, even though implants having the Osseotite® surface are more expensive. Thus, the so-called "nexus" between the claimed implant and the commercial success could not be any more clear since the primary difference between these implants is directly related to their surface topography. MPEP 716.03.

Furthermore, the commercial success of the Osseotite® implants is also expressly acknowledged by competitors, as numerous competitors are trying to market implants with roughened surfaces that tout the alleged advantages of their implants over the Osseotite® implants. The Steri-Oss brochure from 2000 discussed above is just one example. All of this competitive literature is dated between 1998 and 2001, after the clinical success of *3i*'s Osseotite® surface had become well-documented. It is evident that the success achieved by *3i*'s Osseotite® surface caused competitors to market implants that were roughened by neither traditional HA (hydroxy apatite) nor TPS (titanium plasma spray) processes. These competitive

"me-too" products provide substantial evidence that ***3i***'s Osseotite® surface has achieved commercial success throughout the dental implant industry. If ***3i***'s Osseotite® surface were not so successful throughout the dental implant industry, then why would the world's largest suppliers of dental implants be comparing themselves with ***3i***'s Osseotite® implants?

Additionally, the Osseotite® implants establish a long-felt need in that they have a unique ability to provide early osseointegration with bone. Thus, ***3i***'s Osseotite® implants can be loaded as soon as two months after being installed in a patient's mouth. Previously, longer periods of three to six months were thought to be needed. For example, the Schulte article suggests that *"[t]he implant must not be loaded during the healing period of 3 months for the lower jaw and 4 months for the upper jaw."* (see page 6, left column). This "need" is plainly obvious that clinicians and, more importantly, patients would prefer to use a dental implant that is clinically-proven to accelerate osseointegration so as to minimize the healing time before the final prosthesis can be installed on the osseointegrated implant.

In ***3i***'s 1998 FDA submittal attached to Dr. Porter's Declaration as Exhibit C, ***3i*** sought FDA approval of its performance claim that the Osseotite® implants could be loaded in only two months. In doing so, ***3i*** informed the FDA of others who were making similar performance claims. See Section 10 of ***3i***'s FDA submittal. One Canadian company, Inova Corp, provided a performance claim that "Rapid osseointegration with implant loading within 3 months" (not two months) could be achieved by its porous implant surface.

A second company, Straumann, stated that it believed that its SLA surface "would allow a routine reduction of healing times to 6-8 weeks before loading" and that "a clinical study is currently running to demonstrate this [reduction in healing time]." In this May 1998 marketing literature, Straumann further states that implants with its SLA surface would be available in the

United States "later this year" (i.e., in late 1998). Thus, by the time Straumann began selling its SLA implants in the United States, ***3i*** had been selling its Osseotite® implants in the United States for over two years.

A third company, Sargon, did not achieve enhanced osseointegration. Instead, it used an entirely different implant configuration, one where the implant's lower end expands outwardly to compress the bone. Thus, Sargon claimed that this compression in the bone could allow for early loading. Again, this is quite different from ***3i***'s Osseotite® implants, which achieve early loading via enhanced osseointegration due to the claimed implant surface.

Consequently, in addition to its commercial success (but surely related to its commercial success), ***3i***'s Osseotite® implants satisfied a long-felt need for a clinically-proven dental implant that accelerated osseointegration so as to minimize the healing time before the final prosthesis could be installed on the osseointegrated implant.

## VI. Response To Examiner's Rebuttal Arguments

The Examiner has responded to the Applicant's arguments and a reply is in order. The arguments with respect to use of the word "substantially" have been augmented in the above remarks. In essence, the Applicants disagree that the specification lacks enough information to permit one skilled in the art to determine whether a particular process would fall within the scope of the present claims. Not only is the word "substantially" included in the text, but it is commonly used in patent claims where it is necessary to prevent the claims from being given a very narrow interpretation by third parties to avoid infringement.

The Examiner appears to take the position that Example 2, in which all of the native oxide was not removed by exposure to HCl and $H_2SO_4$ alone is within the meaning of a surface which has substantially all of the native oxide removed and having substantially uniform

irregularities. Such an interpretation is clearly not what the Applicants intended. Instead, the purpose of Example 2 was to show that the acid mixture used to create a uniform surface was not effective to remove all of the native oxide, so that while some of the surface may be uniformly etched, those areas covered by residual native oxide were not.

## VII. Information Disclosures

The Applicants include herewith a Sixth Information Disclosure Statement for the Examiner's consideration. The Applicants request that the Examiner review the Fourth Information Disclosure Statement mailed November 13, 2001, and the Fifth Information Disclosure Statement mailed December 18, 2001, neither of which were considered in the Examiner's October 22, 2001, Office Action.

The Examiner is urged to reconsider and withdraw his rejections in view of the amendments and the above remarks. If he believes further amendments may be needed, the Examiner is invited to contact the Applicants' attorney at the telephone number listed below.

Respectfully submitted,

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